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08/967,243 11/05/97 LASKY

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MERCHANT & GOULD
ATTN: DIANE L. MARSCHANG
3100 NORWEST CENTER
90 SOUTH SEVENTH STREET
MINNEAPOLIS MN 55402-4131

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EXAMINER
GAMDEL P
ART UNIT P PAPER NUMBER
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DATE MAILED: 03/10/99

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

- ☒ Responsive to communication(s) filed on 2/17/99
- ☒ This action is FINAL.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.
- A shortened statutory period for response to this action is set to expire 3 months, or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

- ☒ Claim(s) 1, 15-25, 28 is/are pending in the application.
- Of the above, claim(s) 15-25 is/are withdrawn from consideration.
- ☐ Claim(s) is/are allowed.
- ☒ Claim(s) 1, 28 is/are rejected.
- ☐ Claim(s) is/are objected to.
- ☐ Claim(s) are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number)
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received:

- ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- ☐ Notice of Reference Cited, PTO-892
- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s)
- ☐ Interview Summary, PTO-413
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

-SEE OFFICE ACTION ON THE FOLLOWING PAGES-

DETAILED ACTION

1. The request filed 2/17/98 (Paper No. 25) for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 08/967,243 is acceptable and a CPA has been established. An action on the CPA follows.
2. Claims 8-12 and 26 have been canceled. Claims 2-14 and 26-27 have been canceled previously. Claims 15-25, drawn to nonelected inventions have been withdrawn from consideration. Claims 1 and 28 are under consideration and being acted upon.
3. The text of those sections of Title 35 USC not included in this Action can be found in a prior Action. The rejections of record can be found in previous Office Actions (Paper Nos. 7/13/16/23).
4. Applicant should update the status of the parent applications on the first line of the specification. USSN 08/256, 418 is now abandoned.
5. Formal drawings and photographs have been submitted which fail to comply with 37 CFR 1.84. Please see the form PTO-948 previously sent in Paper No. 7.
As pointed out previously, it was noted that applicant has amended the Brief Description of the Drawings to include Figure 2, however there is no Figure 2.
Applicant will submit formal drawings upon the indication of allowable subject matter.
6. Claims 1 and 28 stand rejected under 35 U.S.C. § 112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time the application was filed. The specification as originally filed does not provide support for the invention as now claimed: "inhibiting the binding of native L-selectin to peripheral lymphoid tissue" and "contacting said L-selectin".

The claims now recite inhibiting the binding of "L-selectin" rather than "L-selectin expressing cells" or "L-selectin interactions". Therefore, the claims read on inhibiting soluble L-selectin to peripheral lymphoid tissue rather than inhibiting L-selectin expressing cells from interacting with peripheral lymphoid tissue, as disclosed in the application as filed. Further, the recitation of "native L-selectin" is not readily apparent from the specification as filed. The specification as filed does not provide a written description or set forth the metes and bounds of these phrases. The specification does not provide landmarks nor direction for the instant methods encompassing the above-mentioned "limitations" as they are currently recited. The instant claims now recite limitations which were not clearly disclosed in the specification as-filed, and now change the scope and nature of the instant disclosure as-filed. Such limitations recited in the present claims, which did not appear in the specification, as filed, introduce new concepts and violate the description requirement of the first paragraph of 35 U.S.C. 112.

Applicant is required to cancel the new matter in the response to this Office action

7. Claims 1 and 28 stand rejected under 35 U.S.C. § 112, first and second paragraphs, as the claimed invention is not described in such full, clear, concise and exact terms as to enable any person skilled in the art to make and use the same, and/or for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The instant claims are indefinite in the recitation of "inhibiting the binding of native L-selectin to peripheral lymphoid tissue" and "contacting said L-selectin" because the disclosed and intended claimed methods are drawn to inhibiting the interaction of L-selectin and peripheral lymphoid tissue and to inhibiting L-selectin expressing cells in contrast to the current recitation of inhibiting L-selectin itself. Therefore, the claimed methods are confusing and ambiguous as to the intent of the claimed methods.

There is insufficient direction or guidance provided to assist one skilled in the art in therapeutic methods of "inhibiting the binding of native L-selectin to peripheral lymphoid tissue" in patients of need, wherein the L-selectin or soluble L-selectin is a target of such therapy. Again, the disclosed and intended therapeutic methods are drawn to inhibiting L-selectin mediated interactions and to inhibiting L-selectin expressing cells in patients of need. There is insufficient guidance and direction in the application as filed to treat patients in need, wherein the therapeutic modality is to inhibit L-selectin itself from binding to peripheral lymphoid tissue. Reasonable correlation must exist between the scope of the claims and scope of enablement set forth. It appears that undue experimentation would be required of one skilled in the art to practice the claimed methods using the teaching of the specification alone.

The applicant is reminded that the amendment must point to a basis in the specification so as not to add any new matter.

8. Claim 28 stands objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The recitation of "CD34 isolated from peripheral lymph nodes" recited in claim 28 is essentially the same as that recited in claim 1 and does not further limit claim 1.

9. Claims 1 and 28 stand rejected under 35 U.S.C. § 102(e) as anticipated by or, in the alternative, under 35 U.S.C. § 103 as obvious over Butcher et al. (U.S. Patent No. 5,538,724; see entire document) essentially for the reasons of record set forth in the previous Office Actions (Paper No. 7/13/16/23).

Applicant's arguments and the examiner's rebuttal are of record.

Applicant's arguments have been fully considered but have not been found convincing.

10. Claims 1 and 28 stand rejected under 35 U.S.C. § 102(e) as anticipated by or, in the alternative, under 35 U.S.C. § 103 as obvious over Lasky et al. (U.S. Patent No. 5,304,640) essentially for the reasons of record set forth in the previous Office Actions (Paper Nos. 7/13/16/20).

Applicant's arguments and the examiner's rebuttal are of record.

Applicant's arguments have been fully considered but have not been found convincing.

Applicant's arguments relying upon the Lasky/Rosen/Singer declaration under 37 C.F.R. § 1.132 alone are not found persuasive.

11. Claims 1 and 28 stand rejected under 35 U.S.C. § 103 as being unpatentable over Butcher et al. (U.S. Patent No. 5,538,724) or Lasky et al. (U.S. Patent No. 5,304,640) in view of Lasky et al. (CSHSQB, 1992; 1449, #35), Berg et al. (J. Cell Biol., 1991; 1449, 1449, #8) or Imai et al. (J. Cell Biol. 1991; 1449, #28), Sutherland et al. (Leukemia, 1988; 1449, #51), Lasky et al. (U.S. Patent No. 5,098,833; 1449, #2), Watson et al. (Nature, 1991; 1449, #55), Fina et al. (Blood, 1990; 1449, #22) and Schlingemann et al. (Lab. Invest., 1990; 1449, #42) essentially for the reasons of record set forth in the previous Office Actions (Paper Nos. 7/13/16/23).

Applicant's arguments and the examiner's rebuttal are of record.

Applicant's arguments have been fully considered but have not been found convincing

12. No claim is allowed.


13. All claims are drawn to the same invention claimed in the parent application prior to the filing of this Continued Prosecution Application under 37 CFR 1.53(d) and could have been finally rejected on the grounds and art of record in the next Office action. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing under 37 CFR 1.53(d). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (703) 308-3997. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Phillip Gambel, PhD.
Patent Examiner
Group 1640
Technology Center 1600
March 8, 1999


CHRISTINA Y. CHAN
SUPERVISORY PATENT EXAMINER
GROUP ~~1600~~ 1640